In Extrusion Blow Molding (EBM), plastic is melted and extruded into a hollow tube (a parison). This parison is then captured by closing it into a cooled metal mold. Air is then blown into the parison, inflating it into the shape of the hollow bottle, container or part. After the plastic has cooled sufficiently, the mold is opened and the part is ejected.

EBM processes may be either continuous (constant extrusion of the parison) or intermittent.

Examples of parts made by the EBM process include dairy containers, shampoo bottles, hoses/pipes, and hollow industrial parts such as drums.

Basic polymers, such as PP, HDPE, PVC and PET are increasingly being coextruded with high barrier resins, such as EVOH or Nylon, to provide permeation resistance to water, oxygen, CO2 or other substances. In dairy applications, it is possible to extrude a black light-blocking layer in the center layer of containers, with opaque white resin used in the inner and outer layers.

Compared to injection molding, blow molding is a low pressure process, withtypical blow air pressures of 25 to 150 psi. This low pressure process allows the production of economical low-force clamping stations, while parts can still be produced with surface finishes ranging from high gloss to textured. The resulting low stresses in the molded parts also help make the containers resistant to strain and environmental stress cracking.

[6] An overview of rotational blow molding is available at the following URL:

http://en.wikipedia.org/wiki/Rotational_molding, as reproduced in pertinent part below.

The rotational molding process is a high temperature, low pressure plastic forming process that uses heat and biaxial rotation (i.e. rotation on two axes) to produce hollow, one piece parts.

Critics of the process point to its long cycle times- only one or two cycles an hour can typically occur, as opposed to other processes such as injection molding, where parts can be made in a few seconds. The process does have distinct advantages. Manufacturing large, hollow parts such as oil tanks is much easier by rotational molding than any other method. Rotational molds are significantly cheaper than other types of mold.

The rotational molding process consists of four distinct phases:

1. Loading a measured quantity of polymer (usually in powder form) into the mold.

2. Heating the mold in an oven whilst it rotates, until all the polymer has melted and adhered to the mold wall. The length of time the mold spends in the oven is critical. Toolong and the polymer will degrade, reducing impact strength. If the mold spends too little time in the oven, the polymer melt may be incomplete. The polymer grains will not have time to fully melt and coalesce on the mold wall, resulting in large bubbles in the polymer. This has an adverse effect on the mechanical properties of the finished product.

3. Cooling the mold, usually by fan. This stage of the cycle can be quite lengthy. The polymer must be cooled so that it solidifies and can be handled safely by the operator. This typically takes tens of minutes. The part will shrink on cooling, coming away from the mold, and facilitating easy removal of the part. The cooling rate must be kept within a certain range. Very rapid cooling (for example, water spray) would result in cooling and shrinking at an uncontrolled rate, producing a warped part.

4. Removal of the part.

* * *

Rotationally molded parts have to follow some restrictions that are different from other plastic processes. Being a low pressure process, sometimes designers face hard to reach areas in the mold. Good quality powder may help overcome some situations, but usually the designers have to keep in mind that it's not possible to make some sharp threads used in injection molded goods. Some products based on

page 11, first paragraph. Both extrusion blow molding and rotational molding are widely recognized by those of ordinary skill in the art to produce articles having reasonably uniform wall thickness. Shah Declaration, ¶ 10.

Upon review of the drawings showing an open proximal end portion (e.g., portions 20, 104 defining opening 18) having an outer diameter at least as large or larger as that of the body of the associated tube 10, 100, together with the disclosure suggesting a singular centrifuge tube wall and the fact that such centrifuge tubes are to be made by molding processes that inherently produce reasonably consistent wall thicknesses, one of ordinary skill in the art would readily understand that the application as originally filed discloses "an open proximal end [having] a cross-sectional area at least as large as the average cross-sectional area [of the centrifuge tube body]." Shah Declaration, ¶ 11.

Because whatever is disclosed by the drawings may be added to the specification in words without introducing new matter (*Wolfensberger, supra*), the objection under 35 U.S.C. 132(a) to Applicant's prior amendment to page 8, second full paragraph of the application should be withdrawn. Likewise, the claim rejections under 35 U.S.C. 121, first paragraph should be withdrawn.

2. Centrifuge Tubes are Typically Cylindrical in Shape with an Open Proximal End Having a Cross-Sectional Area That is at Least as Large as the Average Area of the Body

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polyethylene can be put in the mold before filling it with the main material. This can help to avoid holes that otherwise would appear in some areas. This could be also achieved using molds with movable sections.

Rotational molding offers design advantages over other molding processes. With proper design, parts assembled from several pieces can be molded as one part, eliminating high fabrication costs.

The process also has inherent design strengths, such as **consistent wall thickness** and strong outside corners that are virtually stress free. For additional strength, reinforcing ribs can be designed into the part.

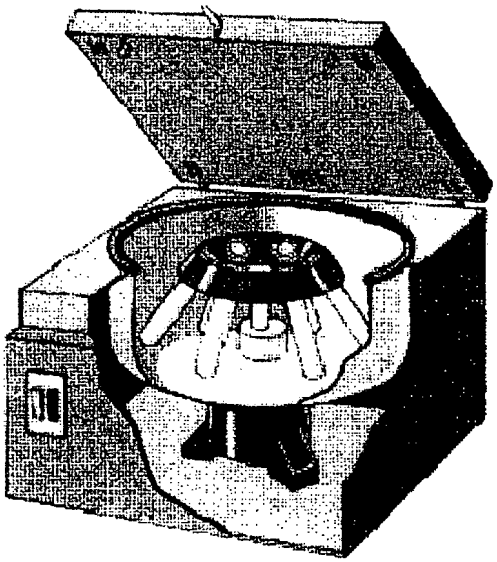
Designers can select the best material for their application, including materials that meet FDA requirements. Additives for weather resistance, flame retardation, or static elimination can be incorporated.

Inserts, threads, handles, minor undercuts, flat surfaces without draft angles, or fine surface detail can be part of the design. Designs can also be multi-wall, either hollow or foam filled.

Products that can be manufactured using rotomolding include storage tanks, bins and refuse containers, doll parts, footballs, helmets, and even boat hulls.

Centrifuge tubes are commonly understood to be substantially cylindrical in shape, occasionally with a conical well. Shah Declaration, ¶ 12. Applicant is unaware of any commercially available centrifuge tube NOT having an open proximal end having a cross-sectional area that is at least as large as an average area of the tube body. Id.

A diagram representing a typical centrifuge containing numerous centrifuge tubes is reproduced below (source: http://www.ktf-split.hr/glossary/en_o.php?def=centrifuge):



Centrifuge is a device in which solid or liquid particles of different densities are separated by rotating them in a tube in a horizontal circle. The dense particles tend to move along the length of the tube to a greater radius of rotation, displacing the lighter particles to the other end.

[Notice that the illustrated tubes are cylindrical in shape.]

See also http://en.wikipedia.org/wiki/Microcentrifuge_tube, stating that "Microcentrifuge tubes or microfuge tubes are small, **cylindrical plastic containers** with conical bottoms, typically with an integral snap cap. They are used in molecular biology and biochemistry to store and centrifuge small amounts of liquid."

As indicated previously, the disclosure of the present application among the drawings and specification text provide a first independent basis for teaching that the application as originally filed discloses "an open proximal end [having] a cross-sectional area at least as large as the average cross-sectional area [of the centrifuge tube]" to one of ordinary skill in the art. Such disclosure is only bolstered by the fact that one skilled the art would understand a centrifuge tube

to typically have an open proximal end having a cross-sectional area at least as large as the average cross-sectional area of the centrifuge tube.

Accordingly, withdrawal of the objection under 35 U.S.C. 132(a) and the rejections under 35 U.S.C. 112 should be withdrawn.

B. Response to Claims Rejections Under 35 U.S.C. 103(a)

The February 20, 2007 Office Action contained multiple rejections under 35 U.S.C. 103(a), including:

- a rejection of claims 22-24, 26-29, 31-33 and 35-38 under 35 U.S.C. 103(a) as being unpatentable for obviousness over U.S. Patent No. 5,255,808 to Tobler ("Tobler") in view of U.S. Design Patent No. 267,076 to Hurtig ("Hurtig"); and
- a rejection of claims 25 and 34 under 35 U.S.C. 103(a) as being unpatentable for obviousness over Tobler, further in view of U.S. Patent No. 3,537,498 to Amand ("Amand").

Such rejections are traversed.

1. Law Regarding Obviousness Rejections Under 35 U.S.C. 103

To support a rejection under 35 U.S.C. 103, the prior art reference(s) must teach all of the limitations of the claims. MPEP § 2143.03.

In considering a reference for its effect on patentability, the reference is required to be considered in its entirety, including portions of teach away from the invention under consideration. Simply stated, the prior art must be considered as a whole. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984); MPEP § 2141.02. "It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art." *Application of Wesslau*, 353 F.2d 238, 241 (C.C.P.A. 1965); *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve*, 796 F.2d 443, 448 (Fed. Cir. 1986), cert. denied, 484 U.S. 823 (1987).

According to the recent U.S. Supreme Court decision in *KSR International Co. v. Teleflex Inc.*, No. 04-1350, 550 U.S. ___ , 127 S.Ct. 1727 (April 30, 2007), the court did not disavow the previous "teaching, motivation or suggestion" or "TSM" test, but stated that such TSM text *should not be strictly applied* in determining obviousness. In connection with this point, the Supreme Court stated that:

> "**A patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art.** ... [Rather], it can be **important to identify a reason that would have prompted a person of ordinary skill in the relevant art to combine the [prior art] elements in the manner claimed.**" *KSR*, slip op. at 14.

It is fundamental to a proper rejection of claims under 35 U.S.C. 103 that an examiner must present a convincing line of reasoning supporting the rejection. MPEP 2144 ("Sources of Rationale Supporting a Rejection Under 35 U.S.C. 103"), citing *Ex parte Clapp*, 227 USPQ 972 (Bd. Pat. App. & Inter. 1985). The Supreme Court in *KSR* affirmed the validity of such approach, stating that "there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."

In *KSR*, the Supreme Court further confirmed that references that teach away from the invention are evidence of the non-obviousness of a claimed invention, (*KSR*, slip op. at pp. 20-23) and reaffirmed the principle that a factfinder judging patentability "should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning."

2. The Particular Shape of Applicant's Centrifuge Tube Serves A Definite Purpose

The February 20, 2007 Office Action erroneously stated that:

> "[t]he particular shape of the body proximal end, uniform, non-uniform, or a cross-section as least as large as the average cross-section fails to solve any stated problem or is for any particular purpose."

(Office Action, page 3.) Such erroneous statement betrays an incomplete or faulty understanding of the present application.

Both of these features directly relate to the primary function of the centrifuge tube – namely, to serve as a container for collection and separation of samples. As noted at page 1 of the application:

> [C]entrifugation processing produces supernatent and pelleted solids, that are amenable to separation, e.g., by decanting of the supernatent liquid from the solids mass in the lower end of the centrifuge tube.

Centrifuge tubes according to various embodiments of the invention include flexural hinges on opposing sides that permit such tubes to be pressed to a flat conformation at the region of local manual deformation. See Application, page 6. As a result of such construction, a specimen-containing swab may be inserted into the centrifuge tube to a point where the user can grasp opposing side surfaces intermediate the opposing side seams and compress the respective sides to define a narrowed slot opening through which the swab element can be drawn to exude or squeeze liquid-borne specimen out of the swab element for subsequent concentration and analysis by the centrifugation operation. See Application, page 6.

To provide such functionality, centrifuge tubes according to the invention should be adapted to receive a specimen-containing swab and exude liquid-borne sample out of the same, and further adapted for use in a centrifuge for effective concentration and analysis.

Conventional centrifuge tubes typically have a substantially cylindrical form, with or without a conical or other narrowed tip to aid in precipitate compaction. Additionally, many centrifuge tubes typically have a diameter of about one inch or less to permit their use with widely available centrifuges of conventional size, and to avoid the need for excessive amounts of wash or elution liquid. Shah Declaration, ¶ 12.

The requirement of claim 22 that the body have "a substantially uniform diameter along the open proximal end" permits the open proximal end to be sufficiently large to receive a specimen-containing swab element without requiring an unnecessarily large and unwieldy tube that may not be suitable for convenient for centrifugation. Shah Declaration, ¶ 13.

Similarly, the requirement of claim 31 that "the open cross-sectional end [have] a cross sectional area at least as large as the average cross-sectional area" ensures that the open proximal end is sufficiently large to receive a specimen-containing swab element without requiring an unnecessarily large and unwieldy tube that may not be convenient for centrifugation, while recognizing that the body may have a non-uniform cross-sectional area along its length. Shah Declaration, ¶ 14.

Mistakenly ignoring all of the foregoing reasons why Applicant's recitation in the claims of a "substantially uniform diameter along the open proximal end" and "the open cross-sectional end [have] a cross sectional area at least as large as the average cross-sectional area" enhanced functionality of the claimed devices, the Examiner opined that:

> "[t]he particular shape of the body proximal end, uniform, non-uniform, or a cross section at least at large as the average cross section fails to solve any stated problem or is for any particular purpose. In fact nowhere in the present disclosure does applicant explicitly set forth a uniform diameter along the open proximal end. Accordingly, it would have been obvious and well within the level of ordinary skill in the art to construct the distal end uniform, for the reason that such a change would have merely been a matter of design choice."

March 23, 2006 Office Action, page 4. Contrary to such opinion, the reasons for claiming the recited features have been plainly described.

3. Patentable Distinctions of Claims Over Tobler and Hurtig

Tobler is not directed to "centrifuge tubes" of any variety – let alone centrifuge tubes embodying the features of the pending claims. Instead, Tobler is directed to foldable bottles (of various shapes including rectangular, essentially round, rectangular/oval, and square/round transverse cross-sections) "distinguished by good stability in the full and empty state as [they have] a large standing surface" (Tobler, col. 2, lines 3-6). Each bottle has a sloping "upper top surface" 4, 104, 204, 304 with a reduced diameter "pouring part" 5, 105, 205, 305 arranged therein. **Tobler thus teaches that the base should be *large* so as to provide stability, with a sloping upper surface leading to a narrowed mouth to facilitate pouring of liquid from the bottle.** Such features of bottles according to Tobler are **CONTRARY** to the "substantially uniform diameter along the open proximal end" limitation of claim 22, and to "the open cross-sectional end [having] a cross sectional area at least as large as the average cross-sectional area" limitation of claim 31. Furthermore, Tobler specifically teaches the presence of a "large standing surface,"

making a bottle according to Tobler ill-suited for use with a centrifuge typically having a small aperture size for receiving a centrifuge tube.

Hurtig – which was assigned to Kraft, Inc, - discloses the ornamental design of a jar. Nothing in Hurtig teaches, discloses, or remotely suggests any centrifuge tube. Furthermore, **the open end of Hurtig's jar is SMALLER than that of the remainder of the body**.

Here, the examiner has failed to consider Tobler in its entirety – i.e., including portions that clearly *lead away* from the claimed invention. It is clear from binding Federal Circuit precedent that failure to consider references in their entirety in fashioning obviousness rejections is improper. *See, e.g., W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984); *see also* MPEP 2141.02. Applicants have already demonstrated herein that Tobler teaches foldable bottles "distinguished by good stability in the full and empty state as [they have] a large standing surface" (Tobler, col. 2, lines 3-6), such that each bottle has a sloping "upper top surface" 4, 104, 204, 304 with a reduced diameter "pouring part" 5, 105, 205, 305 arranged therein. **Tobler thus teaches that the base should be *large* so as to provide stability, with a sloping upper surface leading to a narrowed mouth to facilitate pouring of liquid from the bottle.** Such features directly *contradict* the "substantially uniform diameter along the open proximal end" limitation of claim 22, and to "the open cross-sectional end [having] a cross sectional area at least as large as the average cross-sectional area" limitation of claim 31. Furthermore, Tobler specifically teaches the presence of a "large standing surface," making a bottle according to Tobler ill-suited for use with a centrifuge typically having a small aperture size for receiving a centrifuge tube.

No reasoning that would have prompted a person of ordinary skill in the art to combine Tobler and Hurtig – let alone the "*convincing* line of reasoning" as required to support an obviousness rejection under 35 U.S.C. 103 according to the Supreme Court's *KSR International Co. v. Teleflex Inc.* opinion – **has been advanced by the examiner**. The examiner has plainly engaged in hindsight reconstruction, based on knowledge of the instant application, to try to cobble together a prior teaching of the invention with disparate pieces of non-analogous art. Such hindsight bias is improper, and cannot be used as a basis to reject patent claims.

Given the many teachings of Tobler that contradict the proposed combination with Hurtig, the examiner's failure to consider Tobler *in its entirety* is facially erroneous. But even if there existed some motivation to combine references, the hypothetical combination of Tobler and Hurtig would still NOT yield a centrifuge tube as claimed.

Since all of rejections under 35 U.S.C. 103 of claims 22-24, 26-29, 31-33, and 35-38 are based on Tobler and Hurtig, such rejections must be withdrawn.

With regard to claims 25 and 34, such claims depend from and therefore inherently include all of the limitations of independent claims 22 and 31, respectively. It has already been demonstrated herein that Tobler fails to teach or suggest all of the limitations of claims 22 and 31, and that motivation is lacking to combine Hurtig with Tobler. Such arguments are hereby incorporated by reference as to claims 25 and 34 as if reiterated in their entirety. **Amand fails to supply the teachings missing in Tobler in this regard**. For at least the reason that any combination of Tobler and Amand fails to teach all of the limitations of claims 25 and 34, withdrawal of the rejection of such claims under 35 USC 103 is respectfully requested.

Yet another reason why claims 25 and 34 are patentably distinct over any combination of Tobler and Amand is that **there exists no motivation to combine the teachings of the two references to produce the claimed subject matter – indeed, Amand *teaches away* from making such a combination**. The examiner concedes that Tobler fails to disclose any concave depressions, and points to Amand as teaching a concave depression on an exterior surface facing one another. March 23, 2006 Office Action, pages 4-5. Thereafter, the examiner states that "[i]t would have been obvious to one of ordinary skill in the art to modify the containers of the prior art [i.e., Tobler and Amand] by constructing such a feature" with "the motivation for this modification [being to] permit grasping thereof." *Id.* The proposed combination of Tobler and Amand betrays yet another failure by the examiner to consider prior art references in their entirety (see *W.L. Gore & Associates, Inc. v. Garlock, Inc., supra)* – including portions that lead away from the claimed invention.

Claims 25 and 34 are not merely directed to a bottle having concave depressions; rather, the claims recite, *inter alia*, **centrifuge tubes having integral hinge elements with concave depressions between the hinge elements**, as provided below:

> **25. The centrifuge tube of claim 22, wherein the body comprises concave depressions on an exterior surface of the tube, opposedly facing one another, between the respective integral hinge elements.**
>
> **34. The centrifuge tube of claim 31, wherein the body comprises concave depressions on an exterior surface of the tube, opposedly facing one another, between the respective integral hinge elements.**

Amand is directed to a generally rectangular plastic bottle for storing and dispensing sterile medical liquids. While the examiner correctly points out that the plastic bottle of Amand does include concave depressions on exterior surfaces facing one another, the examiner omits mention of the fact that such indentions are **thickened** to permit the container to be manually grasped **without changing the internal volume of the bottle**. Amand repeatedly refers to the addition need to **avoid flexure problems** that would cause a bottle's internal volume to decrease when grasped. Amand, col. 1, lines 11-42. Amand's teaching to add reinforced wall sections to avoid wall flexure represents a clear ***teaching away*** **from the use of hinge elements** along the outside of a vessel. The present application clearly and repeatedly discusses the desirability of providing a centrifuge tube with integral hinge elements specifically to permit the tube to be pressed to a flat conformation to permit sample to be extracted from a swab element placed into the interior of a bottle. Amand's reinforced regions specifically intended to prevent flexure cannot be construed in any way to disclose or suggest the use of hinge elements intended to enable flexure – and likewise cannot be used to support or motivate any combination of references to yield a structure having integral hinge elements. Since there exists no motivation to combine Tobler and Amand, no *prima facie* case of obviousness exists as to claims 25 and 34 pursuant to MPEP § 2143.01. Accordingly, withdrawal of the rejection under 35 USC § 103 of these claims is respectfully requested.

CONCLUSION

Based on the foregoing, all of Applicants' pending claims 22-29 and 31-38 are patentably distinguished over the art, and in form and condition for allowance. The examiner is requested to favorably consider the foregoing, and to responsively issue a Notice of Allowance. If any issues

require further resolution, the examiner is requested to contact the undersigned attorney at (919) 419-9350 to discuss same.

Respectfully submitted,

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Enclosures:
Declaration of Tilak Shah Under 37 CFR 1.132 [4 pgs.]
Credit Card Payment Form PTO-2038 authorizing $60.00 [1 pg.]

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